ISRCTN49415584 https://doi.org/10.1186/ISRCTN49415584

Patient and surgeon considerations for revision knee replacement for unexplained, chronic pain

Submission date
11/07/2022

Recruitment status
No longer recruiting

Registration date
15/12/2023

Overall study status
Completed

Last Edited
09/01/2024

Condition category
Surgery

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Around one-in-every-five patients reports chronic pain following knee replacement surgery. Many of these patients seek medical help, which prompts the search for a diagnosis to explain their symptoms. However, for a large proportion of patients, no cause is ever found and the pain is said to be 'unexplained'. In this situation, current guidelines recommend initial supportive treatment (for example, with physiotherapy or pain management). Recent evidence suggests around two-thirds of patients will improve with this treatment. However, the remaining one-third of patients remain the same or are worse off. For these patients, the best treatment option is not known, and some patients request a surgical solution. However, surgery to revise a knee replacement for chronic pain is controversial. The surgery itself may be complex and carry a high risk of complications, whilst the odds of an improvement in symptoms are only about 50/50. Our understanding of the important considerations when deciding whether or not to operate for chronic pain are very limited. The aim of this study is to gain a deeper understanding of these considerations from the perspectives of both patients and surgeons. This study will involve interviews with patients and surgeons, which will take place either over the telephone, via videoconference [using Microsoft Teams] or in-person. These interviews will be recorded and analysed using qualitative research methods. This study may benefit patients and surgeons in the future by providing information on the considerations that should be borne in mind when faced with the clinical dilemma of whether to offer revision surgery to treat chronic pain after knee replacement.

Who can participate?
This study is recruiting patients who have unexplained pain after knee replacement and surgeons treating this condition.

What does the study involve?
The study will involve completing a short data collection form to capture information on your background (age, gender, ethnicity, marital status, employment status, dependents, living arrangements, other health conditions, hobbies). This will be followed by an interview where we will ask you about the problems that you have had with your knee replacement, how these have affected you and your thoughts on the role of revision surgery for this problem.

If you decide that you would like to take part, Mr Shiraz Sabah (who is a trainee surgeon undertaking this research as part of a PhD) will contact you to complete a consent form and schedule an interview. The interview will last around an hour. He will discuss with you how you would prefer to be interviewed, with options to do this face-to-face, as a video call or over the telephone. The interview will be audio recorded with consent so that it can be analysed later and sent to an approved transcription service so that it can be typed up word-for-word. The transcription service will be required to delete the recording once the transcript has been returned to us and checked. The researcher will remove information such as names and places that can be used to identify you and add your transcript to our research software under an anonymous identifier (e.g. Participant 1). After we have analysed the interview, we will ask you if you would like to receive a summary to check that we have correctly understood what you told us. We will invite you to provide any feedback or clarifications, but this is optional. We will then write up our findings as a research paper for publication. With your permission, we may use some direct quotations that you have provided us in our reports and publications. These will be anonymised so that they cannot be used to identify you (e.g. Participant 1). We will send you a summary of our main findings at the end of the study.

What are the possible benefits and risks of participating?
This study may not benefit you directly. However, it may benefit patients and surgeons in the future by providing a better understanding of the considerations that are important to you and other patients with chronic pain after knee replacement.

Where is the study run from?
The study is running from the Nuffield Orthopaedic Centre, Oxford and is sponsored by the University of Oxford (UK)

When is the study starting and how long is it expected to run for?
September 2021 to February 2023

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Mr Shiraz Sabah (shiraz.sabah@ndorms.ox.ac.uk)

Contact information

Type(s)
Scientific

Contact name
Mr Shiraz Sabah

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
307265

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 307265, PID 16001, NIHR301771, CPMS 53552

Study information

Scientific Title
A qualitative research study to explore patient and surgeon considerations for revision knee replacement for unexplained, chronic pain

Acronym
Qual rTKR

Study objectives
The purpose of this study is to find out what is important to patients and surgeons when considering further surgery to the knee to treat unexplained, chronic pain after knee replacement

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/04/2022 - HRA and Health and Care Research Wales (Health and Care Research Wales Support and Delivery Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 7976 982591; Wales.REC4@wales.nhs.uk), ref: 22/WA/0090

Study design
Qualitative research study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Patients with painful total knee replacements and surgeons treating those patients

Interventions
Participants who enrol will complete a study questionnaire and undergone one qualitative interview (lasting around one hour).
Participants will be given the option to review their full interview transcript or a summary of it, but will not otherwise be followed up.

Intervention Type
Procedure/Surgery

Primary outcome(s)
To gain a deeper understanding of the important considerations surrounding the decision to operate for unexplained chronic pain after knee replacement and the outcomes most important to patients and surgeons.

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
28/02/2023

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study (including audio recording of interview).
2. Male or Female, aged 18 years or above.
3. Diagnosed with unexplained pain at least 1 year after total knee replacement (Patients only).
4. Currently treats patients with painful knee replacements (Surgeons only).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Non-fluent English speaker (because translation is a form of interpretation)

Date of first enrolment
12/07/2022

Date of final enrolment
01/12/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Nuffield Orthopaedic Centre NHS Trust
Windmill Road
Headington
Oxford
United Kingdom
OX3 7LD

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Not available under terms of research ethics approval.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.1	14/04/2022	12/07/2022	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1.1	14/04/2022	12/07/2022	No	No